

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AMGEN INC.,

Plaintiff,

V.

**AMNEAL PHARMACEUTICALS LLC,
et al.,**

Defendants.

[illegible]

Civ. No. 16-853-MSG
CONSOLIDATED

Goldberg, J.

October 14, 2020

MEMORANDUM OPINION

In this patent infringement action, Plaintiff Amgen Inc. (“Amgen”) sued Defendant Piramal Healthcare UK Ltd. (“Piramal”) based on Amgen’s United States Patent No. 9,375,405 (“the ‘405 patent”) and Piramal’s Abbreviated New Drug Application (“ANDA”) No. 210207 seeking FDA approval to manufacture and sell generic cinacalcet tablets. Currently pending before me is Slate Run Pharmaceuticals, LLC’s (“Slate Run”) motion to intervene pursuant to Fed. R. Civ. P. 24. (D.I. 523). For the following reasons, Slate Run’s motion to intervene will be granted.

I. BACKGROUND

Under a commercialization agreement dated April 3, 2017, Piramal must develop, manufacture, and obtain regulatory approval of its cinacalcet tablets, while Slate Run has the exclusive right to sell and distribute Piramal's tablets in the United States. (D.I. 448 ¶¶ 7- 8). Piramal and Slate Run share the profits from those sales. (*Id.*).

On July 26, 2018, after a four-day bench trial held between March 5, 2018 and March 9, 2018, I issued an opinion finding that Piramal's cinacalcet tablets do not infringe any of the

asserted claims of Amgen's '405 patent, and entered judgment of non-infringement in favor of Piramal and against Amgen. (D.I. 375, D.I. 376, D.I. 386). Amgen timely filed an appeal to the United States Court of Appeals for the Federal Circuit. On August 1, 2018, Piramal received final FDA approval to market its cinacalcet tablets.

On March 6, 2019, while Amgen's appeal was pending, Piramal and Slate Run began selling Piramal's cinacalcet tablets in the United States. (D.I. 447 at 1). On March 19, 2019, Amgen filed an Emergency Motion for an Injunction Pending Appeal to stop the sale of Piramal's cinacalcet tablets. (D.I. 430).

Papers that Amgen attached to its preliminary injunction motion demonstrate that Amgen was aware of Slate Run's role in the sale and distribution of Piramal's cinacalcet tablets and that Amgen sought to stop Slate Run's sale of those tablets. For instance, Amgen attached to its motion the declarations of two experts which both stated that Piramal *and* Slate Run together needed to be enjoined in order to prevent any irreparable harm. *See* D.I. 432 ¶ 19 ("I understand that Slate Run Pharmaceuticals and Piramal Healthcare UK Limited (together, 'Piramal') have launched a generic cinacalcet product and that, if not enjoined by this Court, will continue selling that product."); D.I. 433 at 2 ("Absent injunctive relief in this matter, I expect Amgen to suffer immediate irreparable harm upon the continued launch of a generic version of SENSIP AR® by Slate Run Pharmaceuticals and Piramal Healthcare UK Limited (together, 'Piramal').").

Amgen also attached to its injunction motion a proposed order that directed Piramal "to instruct any entities to whom Piramal has provided such cinacalcet tablets for further distribution or sale (including Slate Run Pharma or Cardinal Health US) that any cinacalcet tablets received from Piramal that are still in the possession, custody or control of such receiving entities must not be further distributed...." (D.I. 430).

In its brief in opposition to the requested injunction, Piramal noted that “Piramal *and Slate Run* are willing to stop selling Piramal’s cinacalcet tablets, pending appeal, if Amgen posts an appropriate bond.” (D.I. 447 at 1 (emphasis added)). Piramal and Slate Run made this offer “to mitigate their potential damages” and “[w]ithout conceding the merits of Amgen’s motion.” (*Id.*). Amgen accepted the offer and drafted several proposed stipulated orders, each of which expressly identified Slate Run as an enjoined entity. (D.I. 537 ¶ 3; D.I. 537-1; D.I. 537-2).

On April 12, 2019, the parties filed a proposed stipulated injunction order which I entered on April 15, 2019 without changes. (D.I. 457; D.I. 462). Relevant here, the order states that “Piramal and its marketing partner, Slate Run Pharmaceuticals, LLC (‘Slate Run’), are enjoined from selling or offering for sale Piramal’s cinacalcet tablets that are the subject of ANDA No. 210207....” (D.I. 462). The order further states, “Pursuant to Fed. R. Civ. P. 62(d), Amgen is required to post a bond in the amount of \$39,000,000.” (*Id.*). The Order set no other terms related to bond. The injunction bond was posted on May 22, 2019. (D.I. 476; D.I. 476-1).

Given the filings and procedural history recounted above there is little doubt that prior to the Federal Circuit’s ruling on my finding of non-infringement, Amgen was well aware of Slate Run’s claim for damages.

On January 7, 2020 The Federal Circuit affirmed my judgment of non-infringement and thereafter entered a mandate on April 22, 2020. (D.I. 491; D.I. 491-1). On June 30, 2020, I entered a scheduling order governing the remaining damages claim based on Piramal’s claim of wrongful injunction. (D.I. 499). On August 6, 2020, Piramal’s counsel requested from Amgen that Slate Run’s counsel be allowed access to highly confidential materials under the existing protective order, because many of the documents and witness statements upon which Piramal intended to rely

upon were from Slate Run. (D.I. 537 ¶ 4). Amgen refused. (*Id.*). Slate Run’s motion to intervene was filed eight days later, on August 14, 2020. (D.I. 523).

II. DISCUSSION

Under Rule 24(a)(2), an applicant has the right to intervene in an action when: (1) “the applicant has a sufficient interest in the litigation”; (2) “the interest may be affected or impaired, as a practical matter by the disposition of the action”; (3) “the interest is not adequately represented by an existing party in the litigation,” and (4) “the application for intervention is timely.” *Harris v. Pernsley*, 820 F.2d 592, 596 (3d Cir. 1987); Fed. R. Civ. P. 24(a)(2). I address each requirement below.

A. Sufficient Interest

An applicant’s interest in the litigation is sufficient if it is specific to the applicant, capable of definition, and directly affected in a substantially concrete fashion by the relief sought. *Commonwealth of Pennsylvania v. President United States of Am.*, 888 F.3d 52, 58 (3d Cir. 2018). Slate Run has a sufficient interest in the litigation. According to Amgen, a launch of Piramal’s cinacalcet tablets before the Federal Circuit decided the appeal would “decimate” the market for Amgen’s cinacalcet tablets, thereby causing irreparable harm. (D.I. 431 at 4). Amgen knew that enjoining Slate Run would prevent the continued sales of Piramal’s cinacalcet tablets. This is because Slate Run had the exclusive right to import and sell those tablets in the United States. (D.I. 448 at ¶¶ 7-10). Thus, Amgen sought and obtained a court order enjoining Slate Run from exercising its exclusive right. (D.I. 462; D.I. 457).

“[A] party is wrongfully enjoined when it turns out that that party had a right all along to do what it was enjoined from doing.” *Nat’l Collegiate Athletic Assoc. v. Governor of New Jersey*, 939 F.3d 597, 603 (3d Cir. 2019). The security bond posted as a condition of the injunction may

be used to pay “costs and damages as may be incurred or suffered by any party who is found to have been wrongfully enjoined.” *Sprint Commc’ns Co. L.P. v. CAT Commc’ns Int’l, Inc.*, 335 F.3d 235, 239 (3d Cir. 2003). Slate Run claims it suffered damages as a result of being wrongfully enjoined and seeks to recover damages from the security bond. (D.I. 524-1 ¶ 3). The remainder of this litigation is scheduled to determine what damages, if any, should be paid out from the security bond. (D.I. 499). Given these facts, Slate Run has a sufficient interest in the litigation.

Amgen disagrees and presses that Slate Run, as a non-party, cannot be enjoined. (D.I. 532 at 12). But this is exactly what Amgen agreed to. Slate Run was enjoined by agreement and indeed Amgen benefitted from that injunction. Having willingly gone down that path and having benefited from the injunction, Amgen is now judicially and equitably estopped from challenging its propriety. *See In re Peck*, 155 B.R. 301, 305-06 (Bnkr. D. Conn. 1993); *see also* 31 C.J.S. Estoppel and Waiver § 156 (June 2020 update) (“The general principle is that the obligors are estopped from denying their liability in accordance with the conditions of the bond, where the bond has subserved the purpose for which it was given and the appellant has had the benefit of it.”).

Amgen further argues that Slate Run cannot recover under the security bond, because it was posted “for Piramal’s sole benefit.” (D.I. 532 at 12). Although there is no explicit language stating that the bond is also for Slate Run’s benefit, the injunction order required Amgen to post a security bond as a condition of obtaining an injunction over both Piramal *and* Slate Run. Accordingly, the bond was not for Piramal’s sole benefit. Because Slate Run was explicitly identified in the injunction order, the cases Amgen cites in support of its argument that a non-party may not recover under the security bond are distinguishable. *See, e.g., Nat’l Wildlife Fed’n v. Nat’l Marine Fisheries Serv.*, 2005 WL 8177174, at *2 (D. Or. June 17, 2005) (rejecting argument that

the bond must be set at an amount to protect against harm to certain third-parties, because those third-parties “have not been restrained or enjoined in any manner”).

B. Impaired Interest

I also conclude that there is a risk that Slate Run’s ability to protect its interests will be impaired by this action. Any damages findings or judgment could have a res judicata or collateral estoppel effect on Slate Run’s interests in recovering its lost profits. The “impaired interest” factor is satisfied if “a determination of the action in the applicants’ absence will have a significant stare decisis effect on their claims.” *Brody ex rel. Sugzdinis v. Spang*, 957 F.2d 1108, 1123 (3d Cir. 1992).

C. Inadequate Representation and Timely Motion

The last two factors—inadequate representation and timely motion—must be addressed together as they overlap. Timeliness is measured from the point at which an applicant knew, or should have known, of the risk to its rights. *United States v. Alcan Aluminum, Inc.*, 25 F.3d 1174, 1182 (3d Cir. 1994); *In re: Syntax-Brilliant Corp.*, 2016 WL 5662074, at *10 (D. Del. Sept. 29, 2016). Thus, a motion to intervene may still be timely even though litigation has already proceeded for several years, because the applicant filed the motion within a few months of learning that its interests were at risk. *Alcan*, 25 F.3d at 1182.

Here, Slate Run filed its motion within days of learning that its interests were at risk. For much of this litigation, Slate Run coordinated with Piramal to ensure that its interests were adequately represented. (D.I. 532 at 15). Then, sometime around August 6, 2020, Piramal’s counsel requested that Slate Run’s counsel be allowed access to highly confidential materials under the protective order because many of the documents and witness statements upon which Piramal intends to rely in presenting the damages claim are from Slate Run. (D.I. 537 ¶ 4). Amgen refused

this request. (*Id.*). As a result, Slate Run no longer had access to the same information as Piramal to make decisions about a damages claim. In addition, Amgen has asserted that only Piramal, and not Slate Run, has a right to recovery under the security bond. (D.I. 532 at 16). For these reasons, the interests of Slate Run and Piramal could diverge, and Piramal may not be an adequate representative of Slate Run's interests. Slate Run filed its motion to intervene within eight days of Amgen's actions that caused the interests of Slate Run and Piramal to diverge. Accordingly, Slate Run's Motion to Intervene was timely.

III. CONCLUSION

For the foregoing reasons, Slate Run's Motion to Intervene is granted. (D.I. 523). An order consistent with this memorandum opinion follows.